510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k060019

B. Purpose for Submission:

Clearance of new device

C. Measurand:

Human chorionic gonadotropin (hCG)

D. Type of Test:

Qualitative colorimetric immunoassay

E. Applicant:

Artron Laboratories, Inc.

F. Proprietary and Established Names:

Artron One-Step hCG Urinary Pregnancy Test

G. Regulatory Information:

1. Regulation section:

   21 CFR §862.1155, Human chorionic gonadotropin (HCG) test system

2. Classification:

   Class II

3. Product code:

   JHI, radioimmunoassay, human chorionic gonadotropin
   LCX, kit, test, pregnancy, hCG, over the counter

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indications for use.

2. Indication(s) for use:

   Artron One-Step hCG Urinary Pregnancy Test Device is intended for the qualitative detection of human chorionic gonadotropin (hCG) in urine to help in the early determination of pregnancy. The device is designed for over-the-counter use as well as professional use.

   For a final diagnosis of pregnancy, a more specific alternative clinical method must be used to obtain a confirmed analytical result.

3. Special conditions for use statement(s):

   For Over-the-Counter use and professional use.

4. Special instrument requirements:

   None required.

I. Device Description:

The Artron One-Step hCG Urinary Pregnancy Test will be sold in three formats: cassette, test strip, and midstream. The test strip and midstream kits consist of one test device and a package insert. The cassette kit consists of one test device and a disposable plastic dropper, and a package insert. Each test device contains mouse monoclonal anti-α-hCG antibody coated membrane and a pad containing mouse monoclonal anti-β-hCG antibody colloidal gold conjugate. The control antibodies are goat anti-mouse IgG.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Victorch hCG Strip
   Wondfo One Step hCG Urine Pregnancy Test

2. Predicate 510(k) number(s):

   k013702
   k043443

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Specimen Type	Urine	Urine
Test Line	Mouse monoclonal anti-alpha hCG antibodies	Mouse monoclonal anti-alpha hCG antibodies
Control Line	Goat anti-mouse IgG	Goat anti-mouse IgG
Detection Antibody	Mouse monoclonal anti-beta hCG antibodies	Mouse monoclonal anti-beta hCG antibodies
Detection Reagent	Colloidal gold	Colloidal gold
Positive result	2 colored lines	2 colored lines
Negative result	1 colored line	1 colored line

Differences		
Item	Device	Predicate
Formats Available	Strip, cassette, midstream	Strip (Victorch) Strip, cassette, midstream (Wondfo)
Cutoff	20 mIU/mL	20 mIU/mL (Victorch) 25mIU/mL (Wondfo)
Assay Time	5-10 minutes	5-10 minutes

K. Standard/Guidance Document Referenced (if applicable):

FDA Guidance document: Guidance for Over-the-Counter (OTC) Human Chorionic Gonadotropin (hCG) 510(k)s

FDA Guidance document: Review Criteria for Assessment of Professional Use Human Chorionic Gonadotropin (hCG) In Vitro Diagnostic Devices (IVDs)

L. Test Principle:

The device is a solid phase, sandwiched immunochromatographic assay. Users are instructed to soak the absorbent pad with urine. The urine will migrate via capillary action toward the result and control window. If hCG is present in the urine it reacts with an anti-HCG-colloidal gold particle conjugate to form a colored line in the test region of the strip. A colored line in the control region of the device indicates adequate sample volume and capillary action. Absence of a colored line in the control region is an indication of an invalid result. Users are instructed to read the device in 5 to 10 minutes.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. *Precision/Reproducibility:*

      See Assay Cutoff Section below.

   b. *Linearity/assay reportable range:*

      Not applicable.

   c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

      This device is traceable to the WHO 3rd International standard.

      Protocols and acceptance criteria were descried for stability testing. The device is stable until the date listed on the labeling.

   d. *Detection limit:*

      To evaluate whether this device demonstrated a high dose hook effect, hCG negative urine specimens were spiked with hCG to concentrations of 62,500, 125,000, 250,000, 500,000, 1,000,000 and 2,000,000 mIU/ml hCG. Results showed that both the test line and the control line were visible at all concentrations tested. However, the sponsor noted that when the hCG level was over 250,000 mIU/ml, the test lines became lighter, potentially indicating that the may a hook effect at some level above 2,000,000 mIU/mL hCG. This study demonstrates that this device shows no hook effect up to 2,000,000 mIU/mL hCG.

   e. *Analytical specificity:*

      To evaluate potential cross-reactivity with similar endogenous compounds, 20 negative urine samples were divided into 3 aliquots each and were supplemented with either luteinizing hormone (hLH), follicle stimulating hormone (hFSH), or thyroid stimulating hormone (hTSH). Results are summarized below (units = mIU/mL).

	500 mIU/mL hLH	1000 mIU/mL hFSH	1000 μIU/mL hTSH
Positive	0	0	0
Negative	20	20	20

To evaluate potential cross-reactivity with similar endogenous compounds, 20 negative urine samples were spiked with 20 mIU/mL hCG, divided into 3 aliquots each, and were supplemented with either luteinizing hormone (hLH), follicle stimulating hormone (hFSH), or thyroid stimulating hormone (hTSH). Results are summarized below (units = mIU/mL).

	500 mIU/mL hLH	1000 mIU/mL hFSH	1000 μIU/mL hTSH
Positive	20	20	20
Negative	0	0	0

To evaluate the potential for interference by certain exogenous compounds, negative urine samples and negative urine samples spiked with 20 mIU/mL hCG were spiked with potential interferants and tested. No interferences were observed at the concentrations tested. The concentrations of substances/conditions that showed no interference are listed below:

Substance/Condition	Concentration Tested	Substance/Condition	Concentration Tested
Acetaminophen	20 mg/dL	Cannabinol	10 mg/dL
Acetlysalicylic acid	20 mg/dL	Ethanol	1 %
Ascorbic acid	20 mg/dL	Methanol	1 %
Caffeine	20 mg/dL	Albumin	2000 mg/dL
Gentesic acid	20 mg/dL	Glucose	2000 mg/dL
Phenylpropanolamine	20 mg/dL	Bilirubin	1000 μg/dL
Salicylic acid	20 mg/dL	Hemoglobin	1000 μg/dL
EDTA	80 mg/dL	pH 9	Not applicable
Benzoylecgonine	10 mg/dL	pH 6	Not applicable
Atropine	20 mg/dL	pH 5	Not applicable

f. Assay cut-off:

To validate the claimed assay cutoff of 20 mIU/mL, the sponsor performed the following evaluation. Negative urine samples from 10 healthy non-pregnant women were pooled together and spiked with hCG to concentrations of 10, 15, 20, 25, 50 and 100 mIU/ml. Forty (40) randomly chosen lay users were asked to perform the test according to the package insert. The results are summarized below. A few samples with hCG concentrations below the cut-off may yield positive results. However, the data support a cutoff claim of 20 mIU/mL hCG.

hCG concentration (mIU/ml)	10 mIU/ml	15 mIU/ml	20 mIU/ml	25 mIU/ml	50 mIU/ml	100 mUI/ml
Total n	40	40	40	40	40	40
Negative	37	30	4	0	0	0
Positive	3	10	36	40	40	40
Percentage of positive reading	7.5%	25%	90%	100%	100%	100%

2. Comparison studies:
   a. *Method comparison with predicate device:*

   Medical professionals from 3 sites tested samples from 120 pateints using the subject device and the predicate device. Results are summarized below :

		Predicate device		**Total**
		Positive	**Negative**	
Artron hCG test	**Positive**	54	2	56
	Negative	0	64	64
	Total	54	66	120

   To evaluate the performance of the device in the hands of lay users, 120 women were asked to test urine samples with the subject device and the predicate according to the package insert. Results are summarized below :

		Predicate device		**Total**
		Positive	**Negative**	
Artron hCG test	**Positive**	46	2	46
	Negative	0	74	74
	Total	46	74	120

   b. *Matrix comparison:*

   Not applicable.

3. Clinical studies:
   a. *Clinical Sensitivity:*

   Not applicable.

   b. *Clinical specificity**:***

   Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Lay users participating in the method comparison study were asked to evaluate the labeling for ease of understanding. All users found the labeling easy to understand.

4. Clinical cut-off**:**

Not applicable.

5. Expected values/Reference range:

All men and healthy non-pregnant females should test negative for hCG.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.